1**Supporting Statement for a Request for OMB Review under The Paperwork Reduction Act**

1. IDENTIFICATION OF THE INFORMATION COLLECTION

1(a) Title and Number of the Information Collection

Title: Revision to Premanufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances [Direct Final Rule; RIN 2070-AJ98]

EPA ICR No.: 0574.16 OMB Control No: 2070-0012

1(b) Short Characterization

This is a request for a revision to an existing information collection request (ICR) that is currently approved under OMB Control No. 2070-0012 (EPA ICR No. 0574.15[1]). The existing ICR addresses the reporting and recordkeeping requirements associated with section 5[2] of the Toxic Substances Control Act (TSCA) (15 U.S.C. 2604), including electronic reporting requirements. EPA is taking direct final action further streamline and reduce the administrative costs and burdens of TSCA section 5 notifications for both industry and EPA. The direct final rule (Attachment 1) amends the TSCA section 5 electronic reporting regulations at 40 CFR Parts 720[3], 721[4], 723[5] and 725[6] by implementing:

- New methods for respondent access to the electronic premanufacture notice (e-PMN) software.
- New procedures for completing the e-PMN form.
- Changes to the CDX registration process for e-PMN submitters.
- A requirement to submit "bona fide intents to manufacture" electronically to EPA.
- A requirement to submit electronically to EPA notifications of any new manufacturing site of a chemical substance for which an exemption was granted by EPA under 723.50.

This ICR revision addresses only the incremental changes to the existing information collection as a result of the direct final rule. Portions of the existing ICR that are not affected by the rule are not addressed in this document.

2. NEED FOR AND USE OF THE COLLECTION

2(a) Need/Authority for the Collection

No Change

[1] OMB ICR Reference No. 201112-2070-001. See: *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201112-2070-001*
[2] See: *http://www.gpo.gov/fdsys/pkg/USCODE-2013-title15/pdf/USCODE-2013-title15-chap53-subchapI-sec2604.pdf*
[3] See: *http://www.gpo.gov/fdsys/pkg/CFR-2014-title40-vol31/pdf/CFR-2014-title40-vol31-part720.pdf*
[4] See: *http://www.gpo.gov/fdsys/pkg/CFR-2014-title40-vol31/pdf/CFR-2014-title40-vol31-part721.pdf*
[5] See: *http://www.gpo.gov/fdsys/pkg/CFR-2014-title40-vol31/pdf/CFR-2014-title40-vol31-part723.pdf*
[6] See: *http://www.gpo.gov/fdsys/pkg/CFR-2014-title40-vol31/pdf/CFR-2014-title40-vol31-part725.pdf*

2(b) Practical Utility/Users of the Data

EPA's electronic reporting program has evolved significantly following the promulgation of the e-PMN final rule in 2010[7]. Following promulgation of that rule, EPA announced web-based electronic reporting workflows for TSCA Chemical Data Reporting, TSCA section 4 test data submissions, TSCA section 8(a) preliminary assessment information rules, TSCA section 8(d) health and safety data reporting rules, and mandatory notifications of substantial risk under TSCA section 8(e) along with related, voluntary "For Your Information" submissions.

Under the current e-PMN rule requirements, TSCA section 5 submitters already must register in CDX and complete an electronic signature agreement before submitting any information to EPA electronically via CDX using the e-PMN software. This direct final rule requires all persons who will be working online on a submission to register with EPA's CDX and to use the e-PMN module within Chemical Information Submission System (CISS) to prepare data for submission. EPA expects that most TSCA section 5 submitters are already registered in CDX. Those users do not need to re-register with CDX, nor will they need to re-verify their identities. In order to use the Thin Client Version of the e-PMN software required under this direct final rule, users who have previously registered with CDX under the TSCA workflow to submit TSCA section 5 submissions, or other CDX workflows such as the Toxics Release Inventory TRI-ME web reporting, will only need to add the "Submission for Chemical Safety and Pesticide Program (CSPP)" CDX workflow to their user profiles. TSCA section 5 submitters who will be new CDX users will now be able to take advantage of a more streamlined CDX registration process that does not involve the submission of signed forms to EPA. In addition, the expansion of electronic reporting requirements to submission of bona fides and new manufacturing site notifications eliminates the need for respondents to maintain multiple systems for providing information to EPA under TSCA as well as the need for EPA to maintain multiple systems for the receipt, processing, and maintenance of those submissions.

3. NON-DUPLICATION, CONSULTATIONS, AND OTHER COLLECTION CRITERIA

3(a) Non-Duplication

No Change

3(b) Public Notice Required Prior to ICR Submission to OMB

Pursuant to the procedures at 5 CFR 1320.5(c)(1) and 1320.10(a), the direct final rule serves as the public notice for this ICR revision.

3(c) Consultations and Public Comments

The Agency has established a public docket for the direct final rule under Docket ID No. EPA-HQ-OPPT-2013-0385, which is available for online viewing at *www.regulations.gov*, or in-person viewing at the EPA Docket Center (EPA/DC), EPA William Jefferson Clinton West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566-1744, and the telephone number for the Pollution Prevention and Toxics Docket is (202) 566-0280.

[7] 75 FR 773, January 6, 2010. See: *http://www.gpo.gov/fdsys/pkg/FR-2010-01-06/pdf/E9-31004.pdf*

Any comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden must be submitted within 30 days of the publication of the direct final rule in the *Federal Register*. Submit any comments, referencing Docket ID No. EPA-HQ-OPPT-2013-0385 and OMB Control No. 2070-0012, to (1) EPA online using *www.regulations.gov* (our preferred method), or by mail to: Document Control Office (DCO), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, Mail Code: 7407M, 1200 Pennsylvania Ave., NW, Washington, D.C. 20460, and (2) OMB's Office of Information and Regulatory Affairs via email to *oria_submissions@omb.eop.gov*, Attention: Desk Officer for the EPA.

3(d) Effects of Less Frequent Collection

No Change.

3(e) General Guidelines

No Change

3(f) Confidentiality

No Change

3(g) Sensitive Questions

No Change

4. THE RESPONDENTS AND INFORMATION REQUESTED

4(a) Respondents/NAICS Codes

No Change

4(b) Information Requested

No Change

(i) Data Items

The underlying requirements for "bona fide intents to manufacture" and for notifications to EPA of any new manufacturing site of a chemical substance for which an exemption was granted by EPA under 723.50 are unchanged. However, they will now need to be submitted to EPA electronically via CDX using the Thin Client e-PMN software system. Bona fides were previously not subject to the electronic reporting requirements of the e-PMN final rule. Also, EPA previously permitted respondents to submit new manufacturing site notifications under 723.50 using the Notice of Commencement (NOC) form. Now that all NOC forms must be submitted to EPA electronically, it is no longer feasible to use that form for the purpose of manufacturing site change notifications. These new manufacturing site

notifications must now be submitted electronically via CDX as a "support document" using the Thin Client version of the e-PMN software.

(ii) Respondent Activities

Within 6 months of the direct final rule, all persons who will be working online on a submission must register with EPA's CDX and use the e-PMN module within CISS to complete their submissions electronically. EPA has prepared a comprehensive user guide for CISS users (Attachment 2) that addresses CDX registration and electronic signatures, general submission preparation and completion, and submission status tracking notifications. This user guide is available at *http://www.epa.gov/oppt/chemtest/ereporting*. EPA has also prepared separate, role-specific user guides for the e-PMN software module in CISS (i.e., the Thin Client Version) (Attachments 3-8), which is available at *http://epa.gov/oppt/newchems/epmn/epmn-index.htm*. An electronic signature is required for TSCA section 5 notices submitted to the Agency via CDX. Electronic signatures are obtained as part of the existing CDX user-registration process.

CDX Registration

EPA expects that most TSCA section 5 submitters are already registered in CDX. Those users do not need to re-register with CDX, nor will they need to re-verify their identities. In order to use the Thin Client Version of the e-PMN software required under this direct final rule, users who have previously registered with CDX under the TSCA workflow to submit TSCA section 5 submissions, or other CDX workflows such as the Toxics Release Inventory TRI-ME web reporting, will only need to add the "Submission for Chemical Safety and Pesticide Program (CSPP)" CDX workflow to their user profiles. TSCA section 5 submitters who will be new CDX users will now be able to take advantage of a more streamlined CDX registration process that does not involve the submission of signed forms to EPA.

As with other electronic TSCA submissions, TSCA section 5 submitters who register with CDX for the first time will be prompted to choose 5 out of 20 offered questions and provide answers to each of those 5 questions. In order to electronically sign and submit data to the EPA or to download the Copy of Record in CDX, a user must correctly answer 1 randomly selected question of the 5 questions chosen by that user (i.e., a "20-5-1" security question) before the transaction can be completed. When the 20-5-1 security question is answered correctly, the thin client version of the software then encrypts the information and transaction is completed.

As with other electronic TSCA submissions, the thin client version of the e-PMN software enables electronic submitters who are newly applying for the Authorized Official (AO) role in CDX to validate their personal identities electronically via LexisNexis. Those submitters applying for the AO role who choose to not use LexisNexis, or for whom LexisNexis could not validate their identities, will need to follow the current, paper-based e-PMN identity validation process. In CDX, these submitters will instead select the "Sign Paper Form" option. CDX will then instruct the user to print, sign, and mail the ESA (ESA processing by EPA may take up to 10 business days from the date of receipt). Since support persons are not able to sign and complete submissions or download the Copy of Record for a submission, they will be able to register with CDX without authentication of identity.

5. AGENCY ACTIVITIES, COLLECTION METHODOLOGY, AND INFORMATION MANAGEMENT

5(a) Agency Activities

EPA is offering an XML schema to those submitters who choose to work on their submissions offline rather than online, which allows them to later upload their information to the Thin Client Version of the e-PMN software for submission using CDX.

5(b) Collection Methodology and Management

Data systems that were populated manually are now populated electronically, reducing the potential for human error that exists when data are entered by hand. Electronically submitted information enables EPA to enhance document management efforts and associate related information (e.g., original submissions, amendments, support documents, etc.). In addition, Agency personnel are also able to communicate more efficiently with submitters electronically, compared to using U.S. mail. Because companies register with EPA to submit their data electronically to the Agency via CDX, the Agency in turn will be able in the future to communicate electronically with submitters via CDX. Some examples of routine communications from EPA that could go through CDX include the Acknowledgment Letter (acknowledging receipt of a submission), and the Incomplete Letter (stating why a submission has been declared incomplete). Currently, these communications are sent through the mail. An electronic means of communication provides significant time and resource savings for both parties.

EPA will no longer accept paper submissions of bona fides and manufacturing site change notifications. They must be submitted to EPA electronically using the e-PMN software. Otherwise, the major difference between the old and new methods of data entry is the electronic reporting tool itself. EPA will no longer make a Thick Client desktop version of the e-PMN software available to TSCA section 5 respondents by a way of a software download from EPA's website or through a compact disc. Submitters of TSCA section 5 notices subject to electronic reporting requirements are now required to use a cloud-based Thin Client version e-PMN software that resides online as part of the CSPP workflow in CDX to complete their submissions. Data now will be entered through a series of pages or screens on the computer. A submission sent to the Agency over the Internet will necessitate an electronic signature. Respondents submitting notices will only need to register once per user for all future electronic submissions. All section 5 notices must be submitted to EPA electronically via CDX using the Thin Client version e-PMN software. The data being transmitted electronically via CDX are encrypted to protect CBI. The software works with Windows, Macs, Linux, and UNIX-based computers, using XML for more efficient data transmittal to Agency data systems that once was performed manually.

5(c) Small Entity Flexibility

No Change

5(d) Collection Schedule

No Change

6. ESTIMATING THE BURDEN AND COST

This section estimates the burden changes for submitters of TSCA section 5 notices that is expected to result from the direct final rule over the annual burden that has already been accounted for in the ICR that is currently approved OMB Control No. 2070-0012. Sections 6(a) and 6(b) estimate the respondents' paperwork burdens and costs, respectively. Section 6(c) estimates EPA costs, section 6(d) summarizes the bottom line burden and costs, section 6(e) describes the reasons for changes in burden from the previous ICR, and section 6(f) presents the burden statement. The economic analysis for the direct final rule[8] provides additional details about the estimated costs and burdens.

6(a) Estimating Respondent Burden

(i) Baseline Adjustments

When EPA last renewed the ICR under OMB Control No. 2070-0012, the Agency erroneously omitted burden calculations for CDX registration activities. While an individual CDX user needs to complete the registration activities only once, companies may continue to designate personnel as CDX users on an ongoing basis. In Fiscal Year 2013, a total of 392 new registrants were approved via CDX for all TSCA section 5 activities (303 TSCA-Authorized Officials (AO) and 89 TSCA-Support Registrants (SR)). EPA estimates that about 10 percent of new CDX registrations will be a result of employee turnover, based on data provided in the ICR for EPA's Cross-Media Electronic Reporting Rule (CROMERR) that is currently approved under OMB Control No 2025-0003[9]. Therefore, approximately 30 new Authorized Officials and 9 new Support Registrants will replace previously registered CDX users for TSCA section 5 activities each year.

EPA assumes that each company will register five employees, and that the burden associated with new CDX user registration activities is the same regardless of whether the registrant is a new employee or is replacing an existing employee. EPA estimates the CDX user registration activities burden to be 0.66 hours per employee (0.18 hours for CDX registration, 0.35 hours for submitting and then verifying electronic signature agreements, and 0.13 hours to establish a Pay.gov account related to the adoption of an electronic payment option for mandatory TSCA fees). With 392 employee registrations per year for TSCA section 5 activities, EPA estimates the annual CDX registration burden to be 258.72 hours (Table 1).

[8] Economic Analysis of the TSCA Section 5 Premanufacture and Significant New Use Notification Electronic Reporting; Revisions to Notification Regulations. The EA is available for online viewing at *www.regulations.gov* in Docket ID No. EPA-HQ-OPPT-2013-0385.

[9] EPA ICR Number 2002.05, OMB ICR Reference No: 201106-2025-001. See: *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201106-2025-001*

Table 1. Baseline Adjustments Associated with New CDX Registration Activities

Title	CDX Registration Burden (Hours)	CDX E-Signature Burden (Hours)	E-Payment (Pay.gov ID account) (Hours)	Total Burden for CDX Registration Activities, (Hours)	Annual Number of New CDX Registrants	Total Annual Burden for CDX Registration (Hours)
Currently Approved	0	0	0	0	0	0
Updated Estimate	0.18	0.35	0.13	0.66	392	258.72
Change	**0.18**	**0.35**	**0.13**	**0.66**	**392**	**258.72**

(ii) Program Changes

Rule Familiarization

The direct final rule requires TSCA Section 5 submitters and their staff to become familiar with the requirements for electronic reporting. Rule familiarization is estimated to require 0.55 hours of technical labor and 0.27 hours of managerial labor, as described in the Economic Analysis of the Premanufacture Notification Electronic Reporting Final Rule, which measures the costs of mandatory electronic reporting of TSCA section 5 notices.

Table 2. Rule Familiarization Burden for TSCA Section 5 Submitters

Title	Rule Familiarization Burden (Hours)	Annual Number of TSCA Section 5 Submitters	Total Annual Burden for Rule Familiarization
Currently Approved	0	0	0
Updated Estimate	0.82	336	275.52
Change	**0.82**	**336**	**275.52**

Electronic Notification of New Manufacturing Sites

As required under 40 CFR 723.50(j)(6)(ii), a manufacturer (including importer) must notify EPA of any new manufacturing site of a chemical substance for which an exemption was granted by EPA under 40 CFR 723.50. Under the existing regulation, companies may use the Notice of Commencement (NOC) to report manufacturing site changes to EPA. However, the electronic version of the NOC in the e-PMN software cannot accommodate notifications of new manufacturing sites. Therefore, the direct final rule requires that such notifications be submitted electronically to EPA via CDX as a "support document" to the original notification.

EPA did not separately estimate respondent burden for new manufacturing site notifications. Such an estimation was not feasible since these notifications were submitted in the past via the NOC form and EPA did not distinguish between normal NOC filings and new manufacturing site notifications. While EPA expects that submitters will encounter minimal burden associated with this new requirement, the incremental burden associated with these notifications is expected to consist of the time it takes a submitter to familiarize themselves with the rule. As a result, this burden has been quantified as a part of the overall rule familiarization burden associated with this ICR.

Electronic Submission of Bona Fides

EPA expects that electronic submission will remove all clerical burden associated with submitting a bona fide (3.5 hours), and all postage costs associated with mailing the notice ($14.21). For each of these notices, one hour of recordkeeping burden will be saved (30 minutes for one technical staff member and 30 minutes for one clerical staff member). Electronic reporting is expected to reduce a respondent's burden by 4.5 hours per bona fide, due to the reduction or elimination of clerical time, and a reduction in recordkeeping burden at clerical and administrative levels, both of which are associated with the new electronic reporting requirement. This program change is estimated to reduce the total annual burden associated with bona fide submissions by about 522 hours; from 2,552 hours to 2,030 hours (see Table 3).

Table 3. Program Changes to Existing ICs Resulting from Electronic Reporting of Bona Fides

Title	Responses	Average Reporting Hours per Response	Total Burden for Reporting	Hours for Recordkeeping	Total Burden for Recordkeeping	Total Burden for Reporting and Recordkeeping
Currently Approved	116	20	2,320	2	232	2,552
Updated Estimate	116	16.5	1,914	1	116	2,030
Change	**0**	**-3.5**	**-406**	**-1**	**-116**	**-522**

6(b) Estimating Respondent Costs

The cost estimates addressed in this section are based on the burden estimates discussed in Section 6(a). Wage rates for each category of personnel, as well as the distribution of paperwork burdens among those categories, are presented in the economic analysis for the direct final rule. The labor cost associated with CDX registration activities, at an average costs of slightly less than $39/response (93 technical registrants and 23 managerial registrants), is estimated to be $4,497/year in the first year. The labor cost associated with rule familiarization, at $56.51/response, is estimated to be and $18,966/year. The labor cost associated with electronically submitted bona fides, at $1,140/response, is estimated to be $134,512/year.

6(c) Estimating Agency Cost

The conversion to an electronic reporting system, as well as the adoption of the Thin Client Version of the software to facilitate form submission and processing, is expected to create long-term burden reductions and efficiencies for EPA. For example, when data is submitted electronically, the time required for EPA staff to review and process the information will be reduced because manual data entry or processing will be eliminated. The use of CDX will enable EPA to notify the submitter that the Agency has received the submission and will lead to higher quality data being available more quickly to EPA.

EPA also expects to realize burden savings attributable to the eventual elimination of its current systems of processing bona fide notices. These savings will stem from eliminating manual data entry of bona fides and related support documents, reducing resources dedicated to quality assurance/quality control (AQ/AC) of the current paper-based system, and either greatly reducing or eliminating operating and maintenance costs for the existing system.

Baseline Agency burden associated with bona fide notices, 2 hours per notice and the Agency extramural cost of $91.74 for contract support. The anticipated Agency burden savings associated with the modified final e-PMN rule are characterized based on information in the CDX *Business Case Analysis* regarding the estimated monetary benefit from using CDX. For this analysis, EPA assumes an average annual savings of 17 percent, for a total post compliance burden of 1.66 hours per notice. As a result of electronic bona fide submissions the Agency expects to save approximately 39 hours and $3,061 annually.

Table 4: Agency Burden Reductions for Electronic Submissions of Bona Fide Intent to Manufacture or Import Notices

	Hourly Burden per Submission	Hourly Agency Wage Rate	Agency Extramural Cost	Total Cost per Submission	Total Number of Submissions	Total Hourly Burden	Total Cost
Baseline	2.00	$77.62	$93.53	$249	116	232	$28,857
Amended	1.66	$77.62	$93.53	$222	116	193	$25,795
Cost Savings	**0.34**			**$26.39**		**39.44**	**$3,061**

6(d) Bottom Line Burden Hours and Cost

The total burden in OMB's inventory for the existing, approved ICR for the TSCA section 5 new chemicals program (EPA ICR No. 0574.15/OMB ICR Reference No. 201112-2070-001) is 117,163 hours. With the adjustment addition of 259 burden hours, and a net program change burden reduction of 246 hours related to the direct final rule, the total burden requested for the TSCA section 5 new chemicals program will be 117,176 hours.

6(e) Reasons For Changes in Burden

The burden changes analyzed in this ICR revision relate to both program changes and adjustments related to EPA's direct final rule. As explained previously, a 259 hour burden adjustment increase is directly related to CDX registration activities that are already required under the e-PMN rule. The adjustment is related to the number of new and replacement employees of firms engaged in TSCA section 5 activities who need to register in CDX. In addition, EPA estimates a program change increase of 276 burden hours associated with respondents' familiarization with the requirements of the direct final rule, as well as a 522 burden hour program change reduction related to the electronic submission of bona fides as required by the direct final rule.

6(f) Burden Statement

The incremental public burden is estimated to average 0.9 hours for per response for CDX registration, 1.8 hours per response for requesting a CDX electronic signature, 0.1 hours per response for establishing an account for electronic fee payments, 0.8 hours for rule familiarization, and 17.5 hours per response for electronically submitted bona fides. Burden is defined in 5 CFR 1320.3(b). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and included on the related collection instrument or form, if applicable.

ATTACHMENTS TO THE SUPPORTING STATEMENT

Attachments to the supporting statement are available in the public docket established for this ICR under docket identification number EPA-HQ-OPPT-2013-0385.

Attachment 1:	TSCA Section 5 Premanufacture and Significant New Use Notification Electronic Reporting; Revisions to Notification Regulations; Direct Final Rule [RIN 2070-AJ98]
Attachment 2:	CDX Chemical Safety and Pesticide Programs (CSPP) Registration User Guide
Attachment 3:	Section 5 Notices and Supports User Guide – Primary Authorized Official
Attachment 4:	Section 5 Notices and Supports User Guide – Primary Agent/Consultant
Attachment 5:	Section 5 Notices and Supports User Guide – Primary Support
Attachment 6:	Section 5 Notices and Supports User Guide – Secondary Authorized Official
Attachment 7:	Section 5 Notices and Supports User Guide – Secondary Agent/Consultant
Attachment 8:	Section 5 Notices and Supports User Guide – Secondary Support